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10/612,852

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Joel S. Douglas

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

APANIUS, MICHAEL

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/612,852

Applicant(s)

DOUGLAS ET AL.

Examiner

Michael Apanius

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20 and 86-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 117-121 is/are allowed.
- 6) ☒ Claim(s) 14-20, 86-105, 113-116 and 122-127 is/are rejected.
- 7) ☒ Claim(s) 106-112 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. This office action is in response to the amendment filed on 11/1/2006. The addition of new claims 103-127 and the amendments to the specification are acknowledged. Currently, claims 14-20 and 86-127 are pending.

Claim Objections

2. Claims 124 and 125 are objected to because of the following informalities: at claim 124, line 3, it appears that "drawing the body fluid into the test strip includes" is improperly worded since a drawing step has not been previously recited in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure fails to provide sufficient support for the claimed method being carried out on a "non-digit body part" as set forth in claim 14.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 86-90, 95, 96 and 98 rejected under 35 U.S.C. 102(b) as being anticipated by Garcia et al. (US 4,637,403). Garcia discloses a method (columns 7-9), comprising: positioning a lancing device (10) in contact with an alternate site, wherein the lancing device houses a disposable (12) that includes a lancet (90) and a test strip (94); forming an incision in the alternate site with the lancet of the disposable; and analyzing the body fluid from the incision with the test strip of the disposable. Note that an alternate site as stated in the claim can be considered a finger tip.

7. In regards to claim 87, the method further comprises expressing the body fluid from the incision with the lancing device before said analyzing.

8. In regards to claim 88, the lancing device includes a stimulator member (the bottom member of the lancing device as shown in figure 4); and said expressing includes pressing the stimulator member around the incision. Note that the bottom of the lancing device is pressed against the finger before actuation and this pressure will inherently express body fluid to some degree.

9. In regards to claim 89, the method further comprises removing the disposable from the lancing device after said analyzing; discarding the disposable after said removing; and loading a fresh disposable into the lancing device (see figure 3).

Art Unit: 3736

10. In regards to claim 90, the disposable includes a capillary and the method further comprises drawing body fluid into the test strip via capillary action (column 8, lines 18-22).

11. In regards to claims 95 and 96, the analysis is performed using an optical or electrochemical technique (column 8, lines 28-33).

12. In regards to claim 98, the lancing device remains in contact with the alternate site during said forming and said analyzing.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 14-20, 97, 99, 101-104 and 113-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) in view of Cusack et al. (US 5,314,441). Garcia discloses the limitations of the claims as noted above. In addition, Garcia discloses moving a capillary from a first position to a second position and a test strip that is disposed along the capillary at the end of the sampling device proximal the skin. The test strip is also considered to be disposed at an end of the sampling device proximal the skin. However, Garcia does not expressly disclose placing the sampling device on a non-digit body part, an earlobe, a limb, or a region of skin where nerve density is low and the supply of body fluid is low. Cusack teaches taking blood samples

Art Unit: 3736

on alternative sites such as a foot, arm or leg for the purpose of obtaining blood samples from neonates or persons with poor circulation (column 1, lines 17-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have placed a sampling device on an arm or leg as taught by Cusack in the method of Garcia in order to obtain a blood sample from neonates or persons with poor circulation.

15. Claims 91-93, 100 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) as modified by Cusack et al. (US 5,314,441) as applied to claims 14-20, 97, 99, 101-104 and 113-115 above, and further in view of Smith (US 5,108,889). Garcia as modified by Cusack does not expressly disclose detecting a drop of the body fluid from the incision is sufficient with a drop sensing mechanism. Smith teaches a drop sensing mechanism that electrically detects the drop and then alerts a user of drop sufficiency for the purpose of ensuring that an adequate sample is obtained for testing (column 25, last paragraph). Note that since the detection occurs during the drawing of the sample, that the detecting step first occurs before a last portion of the drawing step. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a drop sensing mechanism as taught by Smith in the method of Garcia as modified by Cusack in order to ensure that an adequate sample is obtained before testing.

Art Unit: 3736

16. Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) as modified by Cusack et al. (US 5,314,441) and Smith (US 5,108,889), as applied to claims 91-93 and 100 above, and further in view of Morfeld et al. (US 4,562,842). Garcia as modified by Cusack and Smith does not expressly disclose optically detecting the drop. Morfeld teaches that it is known in the art to use an optical detector to determine a sufficient volume of liquid (column 4, lines 3-12). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used an optical detector as taught by Morfeld in the method of Garcia as modified by Cusack and Smith because it is an art-recognized equivalent to an electrical detection means.

17. Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) as modified by Cusack et al. (US 5,314,441) as applied to claims 14-20, 97, 99, 101-104 and 113-115 above, and further in view of Smith (US 5,108,889). Garcia discloses an electrochemical measurement as noted above. However, Garcia as modified by Cusack does not expressly disclose contacting printed electrical circuit paths with electrical leads of an electrochemical meter. Smith teaches contacting printed electrical circuit paths (376 and 378) with electrical leads of an electrochemical meter (330) for the purpose of making an electrochemical measurement. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have contacted printed electrical circuit paths with electrical leads of an electrochemical meter as taught by Smith in the method of Garcia

Art Unit: 3736

as modified by Cusack in order to make the appropriate connections for an electrochemical measurement of an analyte.

18. Claims 122-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) in view of Smith (US 5,108,889). Garcia discloses a method as noted above. The lancet and test strip of the disposable (12) of Garcia move together as a single unit during firing. However, Garcia does not expressly disclose contacting electrical leads of an electrochemical meter to the printed electrical circuit paths of the test strip. Smith teaches contacting printed electrical circuit paths (376 and 378) with electrical leads of an electrochemical meter (330) for the purpose of making an electrochemical measurement. In regards to claim 125, Smith further teaches a pusher (260,264) having the electrical leads that pushes disposables. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have contacted printed electrical circuit paths with electrical leads of an electrochemical meter as taught by Smith in the method of Garcia as modified by Cusack in order to make the appropriate connections for an electrochemical measurement of an analyte.

19. Claims 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) as modified by Smith (US 5,108,889), as applied to claims 122-125 above, and further in view of Cusack et al. (US 5,314,441). Garcia as modified by Smith does not expressly disclose lancing the skin at a region where the

Art Unit: 3736

supply of the body fluid is relatively low as compared to a fingertip. Cusack teaches taking blood samples on alternative sites such as a foot, arm or leg for the purpose of obtaining blood samples from neonates or persons with poor circulation (column 1, lines 17-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have placed a sampling device on an arm or leg as taught by Cusack in the method of Garcia as modified by Smith in order to obtain a blood sample from neonates or persons with poor circulation.

Allowable Subject Matter

20. New claims 106-112 and 117-121 appear to contain allowable subject matter.

21. New claims 106-112 are objected to as being dependent upon a rejected base claim.

Response to Arguments

22. In regards to claim 14, Applicant argues that "non-digit part" is supported by the application as originally filed. In response, it is respectfully noted that this term is never used in the original disclosure. Although the original disclosure appears to support regions other than a finger tip, the original disclosure does not appear to support excluding toes. Non-digit part includes fingers and toes. Therefore, the term introduces new matter into the specification.

23. Applicant argues that the term "alternate site" is definite when used alone. Upon further consideration, the 112, 1st paragraph rejection of claims 86-98 is withdrawn.

Art Unit: 3736

24. In regards to claim 86, Applicant argues that Garcia does not disclose an alternate site since Garcia merely disclose lancing fingers. Moreover, Applicant argues that one of ordinary skill in the art at the time of invention would not have considered a fingertip as an alternate site. In response, it is respectfully noted that a broadest, reasonable interpretation of an alternate site would include a fingertip. For example, one fingertip may be considered an alternate lancing site from another fingertip.

25. In regards to claim 14, Applicant argues that one of ordinary skill in the art, after reading Cusack, would have been motivated away from using the plunge cut systems described in Garcia to form incisions. Applicant's arguments have been considered but are not persuasive. In response, it is respectfully noted that the portion of Cusack relied upon in the rejection is describing conventional blood tests. Cusack notes that incisions are typically made at alternative sites for obtaining blood samples from neonates or persons with poor circulation. Cusack does not correlate the teaching of alternative sites to the type of lancing. Therefore, one having ordinary skill in the art would be motivated to modify the method of Garcia to sample blood from alternate sites as is conventional in the art, to obtain blood from neonates and persons with poor circulation. Moreover, the Applicant admits in the specification that sampling at alternative sites is known in the art and sometimes practiced (page 2, lines 18-19).

26. In regards to claim 99, Applicant argues that Garcia and Cusack do not disclose "expressing the body fluid from the incision with the stimulator sleeve". Applicant goes on to argue that the system of Garcia may barely touch the skin so as to not express fluid or be pressed too hard so as to inhibit fluid expression. It is respectfully noted that

Art Unit: 3736

Garcia discloses pressing the device against the sampling site to cause actuation.

Therefore, the stimulator sleeve of Garcia will be more than barely touching the skin.

Furthermore, it is noted that even an excessive pressure will express some amount of body fluid

27. In regards to new claim 113, Applicant argues that Garcia fails to disclose positioning the passage opening of the capillary passage into contact with the skin after said expressing. In response, it is respectfully noted that Garcia further discloses retracting the needle and capillary halfway as shown in figure 12. Therefore, the capillary passage is positioned into contact with the body fluid while the lancing device remains in contact with the skin after expressing body fluid.

28. In regards to new claim 122, Applicant argues that the electrodes of Smith are contacted as soon as the sensors are loaded and that there is no need to reestablish contact after lancing. In response, it is respectfully noted that since the electrodes are already in contact before and during lancing, the method includes the step of contacting the electrical leads to the circuit paths after forming the incision. The claimed step does not require that the leads are not in contact with the circuit paths before lancing.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3736

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 3736

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA



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